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China Publishes Revised Administrative Measures for Infant Formula Recipe Registration

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Report Highlights:

On June 26, 2019, the State Administration of Market Regulation (SAMR) released the Draft Administrative Measures on Registration of Infant and Young Children Formula Milk Powder Recipes. This draft measure is a proposed revision to the existing Administrative Regulations on Infant Formula Recipes which has been in force since October 1, 2016 (see GAIN report [CH16037](#)). The domestic comment period for this revised draft is open until July 25. Comments should be sent to liuxiaoyi@samr.gov.cn.

Executive Summary:

Since October 1, 2016, domestic and overseas manufacturers of infant formula for sale in China followed the Administrative Regulations on Infant Formula Recipes, published by China's Food and Drug Administration (CFDA, since reorganized into SAMR). On June 26, 2019, SAMR published revised administrative measures as Administrative Measures on Registration of Infant and Young Children Formula Milk Powder Recipes. The domestic comment period is open until July 25, 2019. It is expected that after this domestic comment period, SAMR will notify the latest version of this draft measure to the WTO. There is no anticipated date.

There are significant revisions in this most recent draft. Major changes include, but are not limited to, more stringent requirements for the applicant (e.g., the applicant must possess a complete manufacturing process); shortened timelines for product testing; and more specific requirements regarding on-site audits. Finally, an electronic certification system will be used to manage the infant formula recipe registration process. The following report contains an unofficial translation of the draft regulation.¹

¹ This unofficial translation was generously provided by the European Union Chamber of Commerce in China. Any errors in translation are not to be attributed to the European Chamber.

BEGIN TRANSLATION

Administrative Measures on Registration of Infant and Young Children Formula Milk Powder Recipe (Draft for Comments)

Chapter I General Provisions

Article 1 To ensure strict administration of the registration of infant and young children formula milk powder recipes, and guarantee quality safety of infant and young children formula milk powder, these Measures are formulated with the *Food Safety Law of the People's Republic of China* (hereafter referred to as the *Food Safety Law*).

Article 2 These Administrative Measures apply to the registration of infant and young children formula milk powder recipes that manufactured and sold within, or imported into, the territory of the People's Republic of China.

Article 3 The registration of infant and young children formula milk powder recipes refers to the process during which the State Administration for Market Regulation (hereafter referred to as the "SAMR") reviews the recipes of infant and young children formula milk powder applied for registration according to the process and requirements stipulated in these Measures and decides whether to approve the registration or not.

Article 4 The administration of the registration of infant and young children formula milk powder recipe shall follow the principles of scientific-base, strictness, transparency, fairness and impartiality.

Article 5 The SAMR is responsible for the administration of the registration of infant and young children formula milk powder recipes.

The Food Review Institution of the SAMR (hereafter referred to as the "Review Institution") is responsible for the acceptance and review of the registration of infant and young children formula milk powder recipes. The Review Institution can organise experts in fields such as food safety, food processing, nutrition and clinical medicine to review the registration.

The Audit Inspection Institution of the SAMR is responsible for the on-site audit of infant and young children formula milk powder recipes.

The market regulation departments at provincial, autonomous and municipal level are responsible for cooperating with the SAMR conducting the work of on-site audit of the recipe registration of infant and young children formula and so on.

Article 6 The applicant bears the legal liability and responsibility for the authenticity, integrity and conformity with the laws of the submitted materials.

The applicant shall cooperate with the Market Regulation Departments to conduct registration-related work of on-site verification, sample inspection and so on.

Chapter II Application and Registration

Article 7 The applicant shall be enterprises manufacturing and selling infant and young children formula milk powder within the territory of the People's Republic of China or manufacturers intended to export infant and young children formula milk powder to China.

The applicant shall be equipped with the relevant R&D, production and testing capacity to manufacture infant and young children milk power formula, possess a complete manufacturing process and execute the good manufacturing practice for powdered infant and young children formula, implement the Hazard Analysis and Critical Control Point System, and inspect the products leaving the factory batch by batch for those items stipulated in the relevant laws and regulations as well as food safety national standards for infant and young children formula milk powder.

Article 8 The recipe to be applied for the registration of infant and young children formula milk powder shall comply with the requirements of relevant laws and regulations as well as food safety national standards. Research, development and verification reports and sufficient evidence demonstrating the scientificity and the safety of the recipe shall be provided.

To apply for the registration of infant and young children formula milk powder recipes, the following materials shall be submitted to the SAMR:

- (1) Application form for the registration of infant and young children formula milk powder recipes,
- (2) Credential documents of the applicant,
- (3) Quality and safety standards for raw materials and auxiliary ingredients,
- (4) Product recipes,
- (5) R&D report of product recipe,

- (6) Description of production process,
- (7) Product testing report,
- (8) Materials demonstrating R&D, production and testing capacity,
- (9) Other materials demonstrating the scientificity and the safety of the recipe.

The applicant shall mark the business secret in the application materials according to the relevant provisions and cite the reference.

Article 9 If the same enterprise applies to register more than 2 product recipes for the same age group and product recipes, there shall be significant difference among ingredients of recipes and nutritional properties, which shall be confirmed with scientific evidence. Each enterprise in principle shall not have more than 3 recipe series with 9 product recipes. Each recipe series include infant milk powder formula (0-6 months, Stage 1), older infant milk powder formula (6-12 months, Stage 2) and young children milk powder formula (12-36 months, Stage 3).

Article 10 The recipe registration of infant and young children formula milk powder as well as production license obtained by the parent group company or its wholly-owned subsidiaries can be used by another wholly-owned subsidiary within the same group company or the parent company. Before production, the group company shall evaluate the feasibility adequately and submit written report to the SAMR.

Article 11 The Review Institution shall deal with the applications of the recipe registration of infant and young children formula milk powder according to the following circumstances:

- (1) For the matters in an application that are not subject to registration in accordance with the law, it shall immediately inform the applicant of the rejection,
- (2) For the matters in an application that are not part of SAMR's responsibilities in accordance with the law, it shall immediately make a decision of rejection and inform the applicant of relevant administrative organ to submit application,
- (3) If the applicant is listed in the List of Enterprises with Serious Illegal and Dishonest Acts, it shall immediately inform the applicant of the rejection,
- (4) If the errors of the application materials that can be corrected on the spot, it shall be allowed to make correction by the applicant on the spot,
- (5) If the application materials are incomplete or fail to comply with the statutory form, the applicant shall be informed on the spot or within 5 working days all at once of all contents to be supplemented

and corrected. If it fails to inform so within the time-frame, it will be deemed that the application is accepted upon the day when the application materials are received,

- (6) If the application materials are complete and comply with the statutory form or the applicant submit all supplemented and corrected materials as requested, registration application shall be accepted.

The Review Institution shall issue a dated acceptance certificate stamped with SAMR's specialized seal for administrative permission, no matter whether the application is accepted or not.

Article 12 The Review Institution shall examine the scientificity and the safety of the recipe and the consistency between the product recipe claim and the content of product recipe registration. The Review Institution shall inform the Audit Inspection Institution to carry out the on-site verification according to the actual condition and conduct sampling inspection. The review process shall be completed within 60 working days upon receiving the acceptance materials.

If time extension is needed for review under special conditions, it can be extended to 20 working days upon the agreement of the people in charge of the Review Institution. The decision of extension shall be informed to the applicant in writing.

Article 13 The Review Institution shall inform the applicant of all needed materials of supplement and correction at one time when the Review Institution considers it necessary. The applicant shall provide all materials required within 3 months at one time. The time for preparing materials of supplement and correction will not be included in the review time.

Article 14 The Audit Inspection Institution shall confirm the matters related to on-site verification with the applicant within 3 working days upon receiving the notice from the Review Institution. The applicant shall confirm the on-site verification within 30 working days. The Audit Inspection shall examine the R&D capacity, production capacity and testing capacity of the applicant, as well as the consistency between application materials and the practical situation, complete on-site verification and issue the report within 20 working days upon receiving the confirmation of on-site verification from the applicant.

The Audit Inspection Institution shall notify the provincial market regulation department where the applicant is located to participate in the on-site verification. The provincial market regulation department shall send officials to participate in the verification.

Article 15 The Review Institution shall entrust qualified food inspection institutions to conduct inspection.

The inspection institution shall complete inspection within 20 working days upon receiving the samples according to the food safety national standard and the testing methods submitted by the applicant, and issue the product inspection report to the Review Institution.

Article 16 The Review Institution shall perform review on the application materials, the on-site verification report and product testing report to draw review conclusions.

Article 17 The SAMR shall decide whether to approve the registration or not according to the review conclusion within 20 working days upon receiving the review conclusion from the Review Institution.

The Review Institution shall issue the Certificate of Approval for registration of infant and young children milk powder recipes or the decision of not approval within 10 working days upon the day when the SAMR makes the decision.

Article 18 The time for on-site verification, sample inspection and re-examination shall not be counted in the time of technical evaluation and registration decision. Time of evaluation shall not be included in the time of making registration decision.

The working days for on-site verification and sampling inspection of overseas manufacturers shall be determined based on the practical situation.

Article 19 The application of registration will not be approved under any one of the following circumstances:

- (1) The applicant fails to possess the corresponding R&D, production and testing capacity to manufacture the formula recipe applied for registration.
- (2) The application materials for registration fail to demonstrate the scientificity and the safety of the recipe, or the evidence is not sufficient enough; or the application materials are contradictory or not authentic or fail to comply with the laws and regulations as well as food safety national standards; or the applicant fails to submit materials of supplement within the stipulated time-frame, or the materials of supplement fail to meet the requirements,

- (3) The applicant fails to confirm on-site verification within the time-frame, or refuses or does not cooperate on on-site verification, or the application materials are considered to be false, untraceable or with major defects; or the applicant fails to complete rectification within time-frame,
- (4) The applicant refuses or fails to cooperate with sampling inspection, or the result of the inspection report suggests the applicant is not qualified, or the inspection conclusion shows that the testing method is not scientific or cannot be reproduced,
- (5) If no significant difference can be presented among recipes under application for registration and the recipes of the same age group which have been registered by the same enterprise,
- (6) The applicant is listed in the List of Enterprises with Serious Illegal and Dishonest Acts, it shall immediately inform the applicant of the rejection,
- (7) Any other circumstances fail to comply with relevant registration provisions.

Article 20 The applicant can apply for written application for administrative reconsideration to the SAMR or file an administrative appeal to the people's court whereas the applicant disagrees with the decision made by the SAMR.

Article 21 The Certificate of Approval and attachments shall include the following items:

- (1) Product name,
- (2) The name of the enterprise, the address of manufacture,
- (3) Registration number, approval date, and term of validity,
- (4) Production process,
- (5) Recipes.

The format of the registration number of the approved infant and young children formula milk powder recipes is: Guoshi Zhuzi YP+4 digits of Year + +4 digit of sequence number. YP means infant and young children formula milk powder.

The Certificate of Approval for the registration of infant and young children formula milk powder recipe can be electronic, with the term of validity of the Certificate of Approval being 5 years.

Article 22 Within the term of validity of registration of infant and young children formula milk powder recipes, the applicant shall apply for change of registration if changes need to be made in the Certificate of Approval or items listed in the attachment. Following materials shall be submitted to the SAMR:

- (1) Application form for change of the registration of the infant and young children formula milk powder recipes,
- (2) The product recipe change demonstration report,
- (3) Supporting materials related to the changing matters.

Article 23 If the applicant applies for the changes of the product recipes will impact the scientificity or the safety of the product formula recipes, the Review Institution shall conduct reviews according to the Article 12 in these Measures and actual needs, and draw the review conclusions.

If the applicant applies for the change of enterprise name and production address name (not actual address), the Review Institution shall check and make the changes upon the acceptance.

If the applicant applies for the changes in the product names, labels (instruction) and others which will not impact the scientificity or the safety of the product recipes, the Review Institution shall provide review conclusion within 10 working days upon the acceptance.

The SAMR shall decide whether to approve the change of registration or not according to the review conclusion within 10 working days after receiving the conclusion from the Review Institution. For those that meet the requirements, the SAMR shall go through the formalities for changes in accordance with the law. The date of issue of the Certificate of Approval shall be subject to the date of approval of change of registration. The original registration number and the term of validity of the Certificate remain unchanged. The decision of not approval shall be made when the application of change of registration is rejected.

Article 24 Under the condition that the types of raw materials are unchanged, and the sequence of ingredients list as well as the nutrient composition list are unchanged, the usage amount of food raw materials and food additives in actual production can be reasonably fluctuated or adjusted within a certain range without applying for changes.

If there are differences in the ingredients and nutrient composition table after the change of the product recipe, the product formula registration shall be re-applied.

Article 25 The applicant shall submit the application of renewal to the SAMR 6 months before the expiration of the Certificate of Approval, and also submit the following materials:

- (1) The application of renewal of infant and young children formula milk powder recipes,

- (2) credential documents of the applicant,
- (3) The R&D capacity, production capacity and testing capacity of the enterprise,
- (4) The Self-inspection report of production quality management system of the enterprise,
- (5) The tracking evaluation report of the nutrition and the safety of products,
- (6) Opinions on renewal from the local market regulation departments at provincial, autonomous and municipal level.

The Review Institution shall conduct review on the application of renewal according to the Article 12 in these Measures and to provide review conclusions.

The SAMR shall decide whether to approve the renewal or not according to the review conclusion within 20 working days after receiving the review conclusion from the Review Institution. The SAMR shall renew the Certificate of Approval to the applicant if the renewal is approved. The original registration number will remain unchanged and the term of validity of the certificate shall be recalculated starting from the day of approval of renewal. The SAMR shall decide not to approve the application of renewal if the application is rejected. The application of renewal will be taken as approved if the decision hasn't been made within the time-frame.

Article 26 The application of renewal will not be approved under any one of the following circumstances:

- (1) Fails to apply for the renewal within the stipulated time-frame,
- (2) The applicant fails to conduct manufacturing products following the registration of the product recipes within 5 years,
- (3) The enterprise fails to maintain the R&D capacity, manufacture capacity and testing capacity when registering,
- (4) Any other circumstances fail to comply with relevant provisions.

Article 27 If the procedures for the registration of formula change and renewal of infant formula milk powder products are not specified, the relevant provisions of these Measures on the registration of infant formula milk powder products shall apply.

Chapter III Labels and Instructions

Article 28 The label (instruction) of infant and young children formula milk powder shall comply with the relevant laws, regulations, as well as food safety national standards.

The applicant applying for the registration of infant and young children milk powder recipes shall submit the labels and instruction samples as well as the explanation and demonstration materials claimed in the labels and instruction.

The labels and instruction containing contents of infant and young children milk powder recipes shall be consistent with the recipes that have already been registered, and the registration number shall be marked.

Article 29 Whereas the product name claims on animal origin, the animal origin of dairy ingredients in use such as raw milk, milk powder, whey (protein) powder shall be labelled accurately in the ingredients list according to the product recipe. Whereas the dairy ingredients in use have more than two types of animal origins, the proportion of each animal origin should be labelled respectively.

For edible vegetable oil in the ingredient list of infant and young children formula milk powder, the names of individual types of edible vegetable oil shall be specified in a decreasing order according to the dosage.

Nutritional facts of infant and young children formula milk powder shall be listed according to the sequence of ingredients stipulated in the food safety national standard for infant and young children formula milk powder, and classified into the categories of energy, protein, fats, carbohydrates, vitamins, minerals, optional ingredients and so on.

Article 30 The infant and young children formula milk powder that claims on the ingredient source of raw milk, milk powder ingredients and other dairy ingredients shall specify the country of origin or place of origin.

Article 31 The applicable month age of the infant and young children formula milk powder shall be marked in the claims, and it is also allowed to specify by “Stage1, Stage 2, or Stage 3”.

Article 32 The labels and instruction of infant and young children formula milk powder shall not contain any of the following items:

- (1) Being related to disease-preventing and therapeutic function,
- (2) Expressing or implying that the product has the functions of benefiting intelligence, strengthening the immune system and protecting intestinal tract,

- (3) For substance that shall not be used or will not be contained in the product recipe according to the food safety standards, it is forbidden to use words such as “no addition”, “no contain” and “zero addition” to emphasise the substance is not used / contained,
- (4) False, exaggerated or extreme content, or content against science,
- (5) Vague wording such as the source of raw materials are “imported milk sources”, “origin from oversea dairy farm”, “ecologic dairy farm”, “imported raw materials”, “original ecological milk source” and “pollution-free milk sources” ,
- (6) Contents or claims that is not consistent with the content of the registered product recipe,
- (7) The use of images of infants and women, “human milk”, “breast milk” or similar terms,
- (8) Any other circumstances fail to comply with relevant provisions.

Chapter IV Supervision and Inspection

Article 33 The institutions and personnel who undertake the work of technical review, on-site audit, sampling inspection and approval during the registration of infant and young children formula milk powder recipe shall be responsible for the review conclusions, on-site verification reports, the product test reports and the expert advice issued.

The institutions and personnel who undertake the work of technical review, on-site verification, sampling inspection and approval during the registration of infant and young children formula milk powder recipe shall follow the provisions of the relevant laws, regulations and standards, as well as abide by professional ethics. They shall ensure that the relevant work is scientific, objective and justified.

Article 34 The market regulation departments that receive reports on the illegal behaviours of application acceptance, technical review, on-site verification, sampling inspection, expert argumentation or registration approval during the recipe registration of infant and young children formula milk powder, shall verify and process the case on a timely basis.

Article 35 The SAMR shall release the registration information, label and instruction sample of the registered infant and young children formula milk powder recipes within 20 working days upon approval.

Article 36 The institutions and personnel who undertake the work of technical review, on-site verification, sampling inspection and approval during the registration of infant and young children formula milk powder recipe shall maintain the confidentiality of the trade secret informed.

Article 37 The SAMR can revoke the Certificate of Approval according to its responsibilities or the request of interested parties under any of the following circumstances:

- (1) The approval is granted due to the misuse of authority or dereliction of duty by the personnel,
- (2) The approval is granted by overstepping the legal authority,
- (3) The approval is granted while violating the legal process,
- (4) The approval is granted to the applicant that is not qualified for application or does not comply with the legal qualifications,
- (5) The applicant is listed in the List of Enterprises with Serious Illegal and Dishonest Acts,
- (6) Other legal conditions for revocation of the Certificate of Approval.

Article 38 The SAMR shall cancel the registration of the Certificate of Approval under any of the following circumstances:

- (1) The enterprise applies for cancellation,
- (2) The enterprise is terminated in accordance with the laws,
- (3) The Certificate of Approval expires and is not renewed,
- (4) The registration is revoked, withdrawn or the Certificate of Approval is revoked according to the law,
- (5) Other legal conditions for cancellation of the registration.

Chapter V Legal Liability

Article 39 Whereas there are provisions in the Food Safety Law and other laws regulations on the violations of the registration of infant and young children formula milk powder recipe, those provisions shall prevail.

Article 40 Whereas the applicant conceals relevant conditions or provides false materials or samples to apply for the registration of infant and young children formula milk powder recipe, the SAMR shall not accept the application nor approve the application, give a warning to the applicant, and announce to the public. The applicant shall not re-apply for the registration of infant and young children formula milk powder recipe within 1 year. The applicant being suspected of committing crime shall be transferred to the public security organs for criminal responsibilities according to the laws.

Whereas the applicant obtains the Certificate of Approval by fraud, bribery or other improper means, or concealing relevant real conditions or providing false materials, the Certificate of Approval shall be revoked in accordance with the law by the SAMR. Applications for registration submitted by the applicant will not be accepted within 3 years. The applicant being suspected of committing crime shall be transferred to the public security organs for criminal responsibilities according to the laws.

Article 41 If the applicant fails to organize production according to the registered product formula, manufacturing technology and other technical requirements, the market supervision and administration department at or above the county level shall punish the applicant in accordance with the provisions of Article 124 of the *Food Safety Law*. If the circumstances are serious, the registration certificate shall be revoked.

Article 42 Whereas the applicant fails to apply for modification according to these Measures, which does not impact the scientificity or the product safety, the market regulation departments at or above the county level shall request the applicant to correct and give a warning to the applicant. If the applicant still refuses to correct, a penalty of 10,000 to 30,000 RMB will be imposed to the applicant.

Whereas the applicant fails to apply for modification according to these Measures, which impacts the scientificity or the product safety, the market regulation departments at or above the county level shall impose penalty according to the provisions in the Article 124 of the *Food Safety Law*.

Article 43 Whereas the applicant alters, resells, rents or transfers the Certificate of Approval for the registration of infant and young children formula milk powder recipe, the market regulation departments at or above the county level shall impose a fine from 10,000 to 30,000 RMB. The applicant being suspected of committing crime shall be transferred to the public security organs for criminal responsibilities according to the laws.

Article 44 Whereas the manufacturer or the seller of infant and young children milk powder violates the provisions of Article 28 to Article 32 of these Measures, the market regulation departments shall order the applicant to correct and impose a penalty of 10,000 to 30,000 RMB according to these Measures.

Article 45 Whereas the market regulation departments and their personnel approve the registration of the applicant who is not qualified or approve the registration overstepping the legal authority, actions shall be taken according to the provisions in the Article 144 of the *Food Safety Law*.

Whereas the market regulation departments and their personnel misuse authority, neglect their duties and practice favouritism during the review process, actions shall be taken according to the provisions in the Article 145 of the *Food Safety Law*.

Chapter VI Supplementary Provisions

Article 46 The recipe of infant and young children formula milk powder mentioned in these Measures means all food ingredients, food additives and their dosage used in manufacturing infant and young children formula milk powder, as well as the contents of nutrients in the product.

Article 47 These Measures shall come into force upon promulgation, and the *Management Measures for the Administration of the Registration of Infant and young children formula milk powder Recipes* issued by Order No. 26 of the former China Food and Drug Administration on June 6, 2016 shall be abolished at the same time.

END TRANSLATION